Complete Summary

GUIDELINE TITLE

Use of inhaled nitric oxide.

BIBLIOGRAPHIC SOURCE(S)

American Academy of Pediatrics. Committee on Fetus and Newborn. Use of inhaled nitric oxide. Pediatrics 2000 Aug;106(2 Pt 1):344-5. [21 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Hypoxic respiratory failure

GUIDELINE CATEGORY

Treatment

CLINICAL SPECIALTY

Pediatrics

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To address the conditions under which inhaled nitric oxide should be administered to the neonate with hypoxic respiratory failure.

TARGET POPULATION

Term and near-term newborns with hypoxic respiratory failure.

INTERVENTIONS AND PRACTICES CONSIDERED

Inhaled nitric oxide

MAJOR OUTCOMES CONSIDERED

- Oxygenation
- Need for extracorporeal membrane oxygenation therapy
- Chronic lung disease

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

1. Infants with progressive hypoxic respiratory failure should be cared for in centers with the expertise and experience to provide multiple modes of ventilatory support and rescue therapies or be transferred in a timely manner to such an institution.
2. Inhaled nitric oxide therapy should be given using the indications, dosing, administration, and monitoring guidelines outlined on the product label (further information is available from the U.S. Food and Drug Administration (FDA) Web site). An echocardiogram to rule out congenital heart disease is recommended. Center-specific criteria for treatment failure should be developed to facilitate timely consideration of alternative therapies.
3. Inhaled nitric oxide therapy should be directed by physicians qualified by education and experience in its use and offered only at centers that are qualified to provide multisystem support, generally including on-site extracorporeal membrane oxygenation capability.
4. Generally, inhaled nitric oxide should be initiated in centers with extracorporeal membrane oxygenation capability. If inhaled nitric oxide is offered by a center without extracorporeal membrane oxygenation capability, for geographic or other compelling reasons, mutually acceptable treatment failure criteria and mechanisms for timely transfer of infants to a collaborating extracorporeal membrane oxygenation center should be established prospectively. Transfer must be accomplished without interruption of inhaled nitric oxide therapy.
5. Centers that provide inhaled nitric oxide therapy should provide comprehensive long-term medical and neurodevelopmental follow-up.
6. Centers that provide inhaled nitric oxide therapy should establish prospective data collection for treatment time course, toxic effects, treatment failure, use of alternative therapies, and outcomes.
7. Administration of inhaled nitric oxide for indications other than those approved by FDA or in other neonatal populations, including compassionate use, remains experimental. As such, inhaled nitric oxide should be

administered according to a formal protocol that has been approved by FDA and the institutional review board and with informed parental consent.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Improved oxygenation.
- Reduced need for extracorporeal membrane oxygenation without increased neurodevelopmental, behavioral, or medical abnormalities at 2 years of age.
- Reduced incidence of chronic lung disease.

POTENTIAL HARMS

Potential toxic effects: Methemoglobinemia (secondary to excess nitric oxide concentrations), direct pulmonary injury (attributable to excess levels of nitrogen dioxide), and ambient air contamination.

QUALIFYING STATEMENTS

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The recommendations in this statement do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

Because hypoxic respiratory failure is often rapidly progressive and abrupt, discontinuation of inhaled nitric oxide may lead to worsening oxygenation, the risk of delayed provision of extracorporeal membrane oxygenation must be considered carefully when determining the appropriate time of transfer.

Additional large randomized trials of inhaled nitric oxide in premature neonates are required because they may experience more toxic effects than term and near-term infants.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 Aug

GUIDELINE DEVELOPER(S)

American Academy of Pediatrics - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Pediatrics (AAP)

GUIDELINE COMMITTEE

Committee on Fetus and Newborn

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee on Fetus and Newborn: James A. Lemons, MD, Chairperson; Lillian R. Blackmon, MD; William P. Kanto, Jr, MD; Hugh M. MacDonald, MD; Carol A. Miller, MD; Warren Rosenfeld, MD; Craig T. Shoemaker, MD; Jane E. Stewart, MD; Michael E. Speer, MD

Section Liaisons: Richard Molteni, MD; Jacob C. Langer, MD

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

An update is not in progress at this time.

American Academy of Pediatrics (AAP) Policies are reviewed every 3 years by the authoring body, at which time a recommendation is made that the policy be retired, revised, or reaffirmed without change. Until the Board of Directors approves a revision or reaffirmation, or retires a statement, the current policy remains in effect.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Academy of Pediatrics (AAP) Policy Web site.

Print copies: Available from AAP, 141 Northwest Point Blvd., P.O. Box 927, Elk Grove Village, IL 60009-0927.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on November 16, 2000. The information was verified by the guideline developer on January 8, 2001.

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